

written report required in § 516.145 can be found under § 516.143. Under § 516.141 are provisions for drug companies to nominate a qualified expert panel as well as the panel's recordkeeping requirements. This section also calls for the submission of

a written conflict of interest statement to FDA by each proposed panel member. Index holders are able to modify their index listing under § 516.161 or change drug ownership under § 516.163. Requirements for records and reports are under § 516.165.

Description of Respondents: Pharmaceutical companies that sponsor new animal drugs.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR Section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
516.119	2	1	2	1	2
516.121	30	2	60	4	240
516.123	3	1	3	8	24
516.125	2	3	6	20	120
516.129	30	2	60	20	1,200
516.141	20	1	20	16	320
516.143	20	1	20	120	2,400
516.145	20	1	20	20	400
516.161	1	1	1	4	4
516.163	1	1	1	2	2
516.165	10	2	20	8	160
Total					4,872

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

21 CFR Section	Number of recordkeepers	Annual frequency per recordkeeper	Total annual records	Hours per recordkeeper	Total hours
516.141	30	2	60	0.5	30
516.165	10	2	20	1	20
Total					50

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: November 29, 2010.
Leslie Kux,
Acting Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0566]

Draft Guidance for Industry on Residual Solvents in Animal Drug Products; Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry #211 entitled “Residual Solvents in Animal Drug Products; Questions and Answers.” The draft questions and answers (Q&A) guidance

addresses the United States Pharmacopeia (USP) General Chapter <467> Residual Solvents that applies to both human and veterinary drugs and to compendial and non-compendial drug products. This document answers questions regarding CVM’s implementation of USP <467> Residual Solvents.

DATES: Although you can comment on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by February 1, 2011.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sudesh Kamath, Center for Veterinary Medicine (HFV-145), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8260, e-mail: sudesh.kamath@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On July 1, 2008, the USP implemented a requirement for the control of residual solvents in drug products marketed in the United States. Once implemented, the requirement, USP General Chapter <467> Residual Solvents, became a statutory requirement under section 501(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(b)).

FDA is announcing the availability of a draft guidance for industry #211 entitled “Residual Solvents in Animal

Drug Products; Questions and Answers.” This document answers questions regarding CVM’s implementation of USP <467> Residual Solvents.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in this guidance have been approved under OMB control nos. 0910–0032 and 0910–0669.

IV. Comments

Interested persons may submit to the Division of Dockets Management (*see ADDRESSES*) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.

Dated: November 12, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0533]

Guidance for Industry: Recommendations for Blood Establishments: Training of Back-Up Personnel, Assessment of Blood Donor Suitability, and Reporting Certain Changes to an Approved Application; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled “Guidance for Industry:

Recommendations for Blood Establishments: Training of Back-Up Personnel, Assessment of Blood Donor Suitability and Reporting Certain Changes to an Approved Application” dated November 2010. The guidance document provides recommendations to blood establishments for training of back-up personnel, assessment of blood donor suitability, and how to report certain changes to an approved license application to FDA. The guidance announced in this document finalizes the draft guidance entitled “Draft Guidance for Industry: Recommendations for the Assessment of Blood Donor Suitability, Blood Product Safety, and Preservation of the Blood Supply in Response to Pandemic (H1N1) 2009 Virus” dated November 2009. The guidance announced in this document also is superseding certain recommendations in two previous guidances, the guidance document entitled “Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture” dated July 2001 and the guidance document entitled “Guidance for Industry: Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires” dated July 2003.

DATES: Submit either electronic or written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448. Send one self-

addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Benjamin A. Chacko, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled “Guidance for Industry: Recommendations for Blood Establishments: Training of Back-Up Personnel, Assessment of Blood Donor Suitability and Reporting Certain Changes to an Approved Application” dated November 2010. The guidance document provides recommendations to blood establishments for training of back-up personnel, assessment of blood donor suitability, and reporting certain changes to an approved license application to FDA.

In the **Federal Register** of November 19, 2009 (74 FR 59982), FDA announced the availability of the draft guidance entitled “Draft Guidance for Industry: Recommendations for the Assessment of Blood Donor Suitability, Blood Product Safety, and Preservation of the Blood Supply in Response to Pandemic (H1N1) 2009 Virus” (November 2009). At that time, we anticipated that the rapid spread of pandemic (H1N1) 2009 virus had the potential to cause disruptions in the blood supply and that the usual practices for ensuring blood availability in response to local disasters (*i.e.*, hurricanes) would not be applicable or sufficient under a severe pandemic scenario. Since we issued the draft guidance, the H1N1 influenza pandemic has waned in the United States and disruptions in the blood supply have not been observed. Therefore, we are not finalizing those recommendations set forth in the draft guidance that referred to blood donor deferral and blood product management specific to the pandemic (H1N1) 2009 virus. Instead, we are finalizing those recommendations contained in the draft guidance that are of general